


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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|--|---|---|----------------------|
| Applicant's or agent's file reference NO 7613WO | FOR FURTHER ACTION | | See Form PCT/PEA/416 |
| International application No. PCT/EP2004/011470 | International filing date (day/month/year) 13.10.2004 | Priority date (day/month/year) 13.10.2003 | |
| International Patent Classification (IPC) or national classification and IPC A61K35/72 | | | |
| Applicant NESTEC S.A. et al | | | |
| 1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 7 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). | | | |
| 4. This report contains indications relating to the following items: <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application </div> | | | |
| Date of submission of the demand 11.05.2005 | | Date of completion of this report 11.10.2005 | |
| Name and mailing address of the international preliminary examining authority: <div style="margin-left: 20px;">  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016 </div> | | Authorized Officer Bayrak, S Telephone No. +31 70 340- | |



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/011470

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-11 as originally filed

Claims, Numbers

1-9 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-9 (all partially)

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 1-9 (all partially) (see separate sheet)

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
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International application No.
PCT/EP2004/011470

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|---------|
| Novelty (N) | Yes: Claims | 3-8 |
| | No: Claims | 1,2,9 |
| Inventive step (IS) | Yes: Claims | 3-5,7-9 |
| | No: Claims | 1-9 |
| Industrial applicability (IA) | Yes: Claims | 1-9 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item III.

1. Present claims 1-9 relate to a compound defined by reference to a desirable characteristic or property, namely "yeast extract" or "meat extract". The claims cover all compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the compound by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible.

2. Claims 1-9 relate to the use of a pharmaceutical preparation for the treatment of "the effects of infection by enterotoxin-producing pathogens", "failure of gut epithelia integrity", "other COX-2 mediated effects...", which encompass a multitude of different diseases. The claims thus cover a rather large number of diseases, whereas the application provides support within the meaning of Article 6 PCT and disclosure within the meaning of Article 5 PCT for only a very limited number of diseases. Consequently, the claims lack support and the application lacks disclosure. Independent of the above reasoning, the claims 1-9 also lack clarity because it is not fully possible to determine the diseases for which protection might legitimately be sought (Article 6 PCT).

Consequently, the search has been carried out for those parts of the application which do appear to be clear, namely the use of the compositions as clearly specified in the examples of the present application for the prevention/ therapy of diseases mentioned in the description such as diarrhea, colitis, dysentery, mucosal ulceration, haemorrhagic inflammatory exude, gastritis, inflammatory bowel disease, irritable bowel syndrome, intestinal cancer; and with due respect to the general idea of the invention.

No opinion will be given in respect of subject matter which is not covered by the search report (Rule 66.1(e)PCT)

Re Item V.

The following documents are referred to in this communication:

D1: US 2002/155126
D2: US-A-5 665 352
D3: US-A-4 643 897
D4: US-A-4 595 590
D5: XP001022122
D6: XP008030503

1 NOVELTY (Art. 33(2) PCT)

1.1 The present application does not meet the requirements of Article 33(2) PCT, because the subject-matter of claims 1,2,9 is not new in respect of the prior art as defined in the regulations (Rule 64(1)-(3) PCT):

D1 discloses the use of yeast extract (yeast cell wall fraction from *S. cerevisiae*) for the treatment of inflammatory bowel disease, ulcerative colitis, constipation, inhibition of diarrhea. The composition may further contain meat extract (steamed fish paste)(cf. claims and par. 0031).

The applicant's attention is drawn to the fact that "yeast extract" is also intended to cover an "extract comprising both soluble and insoluble portions of autolysed bakers' yeast" (cf. page 3, line 29-30 of the present application)

Therefore, the subject matter of claims 1,2,9 is not new (Article 33(2) PCT).

2 INVENTIVE STEP (Art. 33(3) PCT)

2.1 Even if novelty could be established for claims 1,2,9, the present application would not meet the requirements of Art. 33(3) PCT in view of document D1 because the subject-matter of the claims 1,2,9 appears not to involve an inventive step in the sense of Art. 33(3) PCT. The same applies to the subject-matter of the claims 3-8 which apparently does not contain any technical

features which could be regarded as inventive per se.

Moreover, the use of yeasts of the genus *Saccharomyces* such as *Saccharomyces boulardii* or *Saccharomyces cerevisiae* was well known in the prevention and treatment of diseases of the G.I. tract. Document D2 discloses the use lyophilised yeast for the therapy of cryptosporidium diarrheas (cf. whole document). Document D3 discloses the use lyophilised yeast for the therapy of dysenteric amoeba (cf. whole document). Documents D4 and D5 disclose the use lyophilised yeast (*Saccharomyces boulardii*) for the therapy of pseudo-membranous colitis, induced especially by *Clostridium difficile* (cf. whole document). Document D6 discloses the use of lyophilised *Saccharomyces boulardii* for the therapy of sever acute diarrhea in children.

3 INDUSTRIAL APPLICABILITY (Art. 33(4) PCT)

3.1 Claims 1-9, insofar as clear, fulfil the requirements of (Article 33(4) PCT).